DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

March 27, 2001

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-33

John R. Swanes, Owner
Northern Fish Products, Inc.
3911 South 56th Street
Tacoma, Washington 98409

WARNING LETTER

Dear Mr. Swanes:

We inspected your firm located at 3911 South 56th Street, Tacoma, Washington, on October 26, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (Seafood HACCP regulations). A FDA 483 form listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your hot smoked products, histamine/scrombroid-toxin forming species, and cooked ready-to-eat products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

Hot Smoked Products (Natural and Kippered) HACCP plan

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for Hot Smoked Products lists a critical limit of "the core temperature from the coldest piece (piece in the coolest part of the smoker) from each batch will be no less than 150 °F (65 °C) at end of cook process" at the Smoking and Cooking Step critical control point that is not adequate to control "kill all pathogenic bacteria present" (i.e. – Pathogen survival through cooking). You did not list a time measurement to show how long the product will be cooked with a core temperature of 150°F.

2. You must implement a record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(c)(7). Your firm did not record monitoring observations at the Smoking and Cooking critical control point to control for "pathogenic survival through cooking" listed in your plan.

3. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). Your corrective action plan for Hot Smoked Products at the

   a. Smoking and Cooking Step critical control point to control "kill all pathogenic bacteria present" (i.e. – Pathogen survival through cooking) is not appropriate. The plan does not address how you will prevent the deviation from recurring.
   b. Final Cooking critical control point to control "microbial recontamination" (i.e. – Pathogen growth and toxin formation) is not appropriate. Sensory evaluation alone is not an effective method to evaluate the safety of the product. In addition, the plan does not address how you will prevent the deviation from recurring.
   c. Refrigerated Storage critical control point to control" outgrowth of pathogenic bacteria" (i.e. – Pathogen growth and toxin formation) is not appropriate. Sensory evaluation alone is not an effective method to evaluate the safety of the product. In addition, the plan does not address how you will prevent the deviation from recurring.

4. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). Your firm's HACCP plan for Hot Smoked Products does not list the food safety hazard of Food Additives, specifically undeclared Yellow #6.

5. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plan for Hot Smoked Products lists

   a. A monitoring procedure at the Final Cooling critical control point that is not adequate to control "microbial recontamination" (i.e. – Pathogen growth and toxin formation). The procedure should include a statement that the time and temperature will at a minimum be recorded when the temperature is "40°F or less" or when the time reaches 4 hours, whichever comes first.
   b. A monitoring frequency at the Refrigerated Storage critical control point that is not adequate to control "outgrowth of pathogenic bacteria" (i.e. – Pathogen growth and toxin formation). The frequency of "everyday" is not sufficient to ensure that the temperature of the products will not be greater than 40°F during storage.

Histamine/Scrombroid Toxin Forming Species and Cooked/Ready to Eat Products HACCP plan

1. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). Your corrective action plan for:

   a. Histamine/Scrombroid-Toxin Forming Species at the
      1. Receiving at Supplier critical control point to control formation of histamine is not appropriate. The plan does not address how you will prevent the deviation from recurring.
      2. Receiving at Plant critical control point to control formation of histamine is not appropriate. The plan does not address how you will prevent the deviation from recurring.
      3. Refrigerated Storage critical control point to control formation of histamine is not appropriate. Sensory evaluation alone is not an effective method to evaluate the safety of the product. In addition, the plan does not address how you will prevent the deviation from recurring.
   b. Cooked/Ready-to-Eat Products at the Receiving and Refrigerated Storage critical control points to control outgrowth pathogenic bacteria is not appropriate. Sensory evaluation alone is not an effective method to evaluate the safety of the product. In addition, the plan does not address how you will prevent the deviation from recurring.

2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). Your firm's HACCP plan for:

   - Histamine/Scrombroid-Toxin Forming Species lists a critical limit of "the temperature of these products will be no greater than 40°F (4.4°C) at time of receiving" at both the Receiving at Supplier and the Receiving at Plant critical control points that is not adequate to control histamine formation. The critical limit does not address abuse that may occur during transportation.
   - Cooked/Ready-to-Eat Products lists a critical limit of "the temperature of these products will be no greater than 40°F (4.4°C) at time of receiving" at Receiving critical control point that is not adequate to control outgrowth pathogenic bacteria. The critical limit does not address abuse that may occur during transportation.

3. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). Your firm's HACCP plans for Histamine/Scrombroid-Toxin Forming Species and Cooked/Ready-to-Eat Products list a monitoring frequency at the Refrigerated Storage critical control point that is not adequate to control outgrowth of pathogenic bacteria. The frequency of "everyday" is not sufficient to ensure that the temperature of the products will not be greater than 40°F during storage.

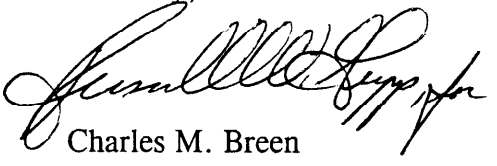
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Lisa Eland at (425) 483-4913.

Sincerely,



Charles M. Breen
District Director

Enclosures:
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA with disclosure statement